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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,710	02/24/2004	Mark L. Nelson	PAZ-025CPCNRCE	3651
959	7590	09/04/2007	EXAMINER	
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			HAVLIN, ROBERT H	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			09/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/786,710	Applicant(s) NELSON ET AL.	
	Examiner Robert Havlin	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14, 16, 19, 21, 23-26, 30-40, 56-68, 82 and 103-154 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 16, 19, 21, 23, 24, 30-40, 82 and 139-154 is/are rejected.
- 7) ☒ Claim(s) 25, 26, 56-68, 103-138 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

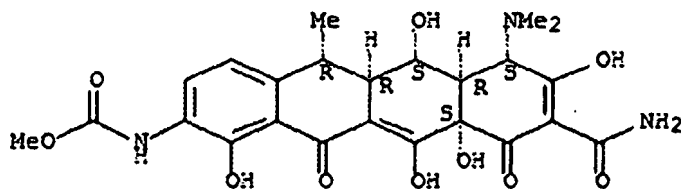
## DETAILED ACTION

### *Double patenting*

The double patenting rejections of claims 1-4, 6-14, 16, 19, 21, 23, 24, 30-40, and 82 are maintained and are expanded to include newly presented claims 140-154 since the claims are read on the same subject matter as those rejected in the previous office action.

### *Claim Rejections - 35 USC § 103*

The examiner has considered the applicant's remarks regarding the rejection under 35 USC 103(a) and not found them persuasive. As stated in the prior office actions one of ordinary skill in the art would know to look to homologues to find the compound with the optimal activity. Since R9a is defined as "absent" or "a prodrug moiety" in the instant claims this clearly does not make it patentably distinct from compounds where the same position is methyl as in the compound taught by Barden et al.:



According to the specification

"prodrug moiety" includes lower-alkyl esters which corresponds to the teachings of Barden et al. including the specific compound above.

Applicant's efforts to amend the definition of R9a to overcome the rejection are insufficient. Therefore, the 103(a) rejection of claims 1-4, 11-13, 16, 18, 19, and 82 are maintained.

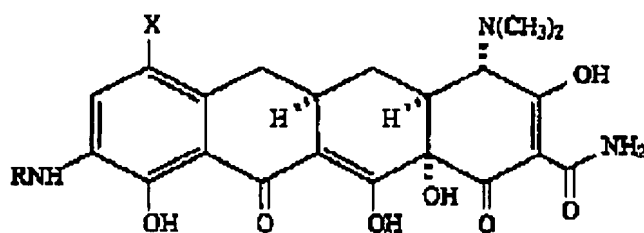
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The 35 USC 103(a) rejection is additionally applied to the newly presented claims 140-146, 148, and 154 since one of ordinary skill in the art would have the knowledge to immediately recognize homologues of the teachings of Barden et al. would be useful for the same purpose. Furthermore, the claimed subject matter is the same as taught by Barden et al.

### ***Claim Rejections - 35 USC § 102***

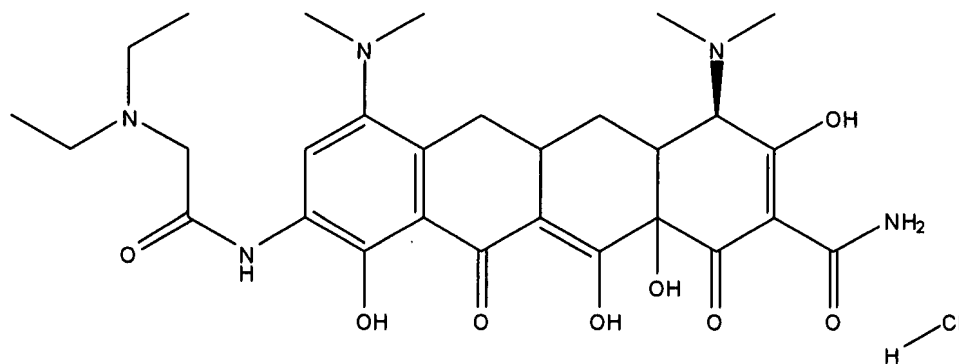
1. Claims 140-146, 148-150, and 154 are rejected under 35 U.S.C. 102(b) as being anticipated by Hlavka et al. (US 5,494,903).

Hlavka et al. teaches compounds of the formula



and specifically compounds such

as in claim 61:



4S-4,7-Bis(dimethylamino)-9-[[[(diethylamino)acetyl]amino]-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-2-naphthacenecarboxamide hydrochloride

***Claim Rejections - 35 USC § 112***

2. The rejection of claim 139 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. As stated in the previous office action there is no way of determining the meets and bounds of a claim generically defined as a "substituted" compound.

***Conclusion***

Claims 25, 26, 56-68, 103-138 are rejected for being dependent on a rejected base claim. No claims are in condition for allowance. Since any new grounds for rejection in this action was necessitated by the applicant's amendment, this action is made final.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

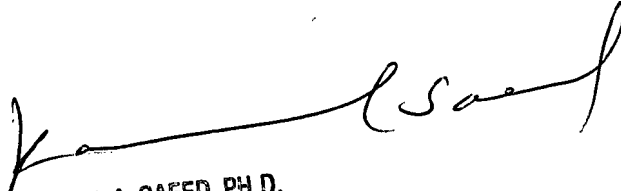
If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin  
Examiner

RH



KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER